RPC

MAY - 8 2009

510(k) SUMMARY

Prepared:	February 6, 2009
Submitter:	Reprocessing Products Corporation (RPC)
Address:	3655 N. Oracle Road Tucson, AZ 85705
Phone:	520-888-5551
Fax:	(Fax) 520-888-5557
Contact:	Michael Honstein, Chief Operating Officer
Device Trade Name:	Two ranges: Ultra Low Total Chlorine (K100-0118) and E-Z Chek® Sensitive Total Chlorine (K100-0106) Test Strips
Common or Usual Name:	Total Chlorine Test Strips
Device Classification Name:	Strip, Test, Reagent, Residuals for Dialysate, Disinfectant
Product Code:	MSY
Class:	II
Regulation Number:	875.5665
Substantial Equivalence:	The RPC Total Chlorine Test Strips are substantially equivalent to the SERIM® HISENSE ULTRA 0.1™
Device Description:	Device is semi-quantitative, reagent test strip comprised of a pad impregnated with chemicals which change color upon contact with Free Chlorine or Chloramines. The pad is attached to a plastic strip for handling.
Intended Use:	The RPC Total Chlorine Test Strips are indicated for use in the monitoring of chlorine in water used to prepare dialysate and water used to rinse dialysis equipment.
Technological Characteristics:	The Test Strips will detect chlorine concentrations equal to, above and below 0.1 ppm for Total Chlorine in water used to prepare dialysate and 0.5 ppm for Free Chlorine in dialysis equipment rinse water. The test strip pad contains a specialized chemical reagent that reacts with Free Chlorine and Chloramines in water. The reaction results in a color change which is correlatable to the concentration of chlorine in the test water.

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	The color change is interpreted by the use of color blocks on two separate (ranges) color charts. Gradations for the Ultra-Low Total Chlorine (K100-0118) color chart include 0 ppm, 0.01 ppm, 0.02 ppm, 0.05ppm, 0.1ppm, 0.15ppm, 0.2 ppm. Gradations for the E-Z Chek® Sensitive Total Chlorine (K100-0106) color chart include 0 ppm, 0.1 ppm, 0.5 ppm and 3.0 ppm.
Performance:	The data confirm the product consistently generates color change which correlates with the color block for the Reference solution concentration. Reference solutions were used to evaluate performance between 0 and 10 ppm Chlorine. These data demonstrate accurate detection performance, below, equal to, and above the dialysis level of 0.5 ppm for Free Chlorine and below, equal to, and above the dialysis level of 0.1 ppm for Chloramines (measured as Total Chlorine). These data demonstrate appropriate performance for use in testing dialysis equipment rinse water and for testing water for dialysate preparation.
Conclusion:	The RPC Total Chlorine Test Strips have the same intended use as the predicate device. Both test strips measure total chlorine (free chlorine/chloramines) levels in water. The RPC Total Chlorine Test Strips have no characteristics which raise new types of safety and effectiveness questions. The RPC Total Chlorine Test Strips can be used to monitor the level of total chlorine (free chlorine/chloramines) present in water used for preparation of dialysate. The test strips can also be used to detect residual chlorine levels in rinse water from dialysis equipment after disinfection.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2009

Reprocessing Products Corporation
c/o Mr. Wally Jansen
President
MedReg Consulting
8662 Comstock Lane N
MAPLE GROVE MN 55311

Re: K090338
Trade/Device Name: Ultra Low Total Chlorine (K100-0118) and E-Z Check® Sensitive Total Chlorine (K100-0106) Test Strips
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: MSY
Dated: February 6, 2009
Received: February 24, 2009

Dear Mr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

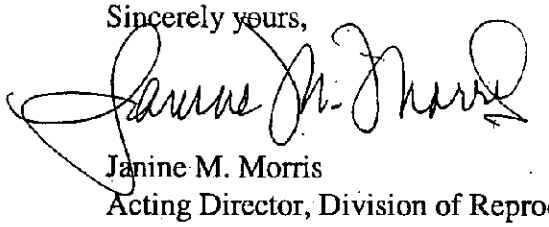
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090338

Indications for Use

510(k) Number (if known):
K090338

Device Name:
Ultra Low Total Chlorine (K100-0118) and E-Z Check ® Sensitive Total Chlorine (K100-0106) Test Strips

Indications For Use:
The Reprocessing Product Corporation (RPC) Total Chlorine Test Strips are indicated for detection of Free Chlorine and Total Chlorine in water. These Test Strips are indicated for testing water used to prepare dialysate (Free Chlorine and Chloramines) and for testing rinse water following dialysis equipment disinfection (Free Chlorine).

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Colin M Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090338